DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
New Orleans District
Nashville Branch Office
297 Plus Park Blvd.
Nashville, TN 37217

Telephone: 615-781-5380
Facsimile: 615-781-5391

March 1, 2005

Warning Letter No. 2005-NOL-13

FEDERAL EXPRESS
OVERNIGHT DELIVERY

Stephen E. Zwick, President
Professional Specialties Company
dba Profex Medical Products
2224 East Person Avenue
Memphis, Tennessee 38114-3629

Dear Mr. Zwick:

On January 10-12, 2005, an investigator from the Food and Drug Administration (FDA) conducted an inspection of your facility, Professional Specialties Company, doing business as Profex Medical Products, 2224 East Person Avenue, Memphis, Tennessee 38114-3629. This inspection determined your firm to manufacture protective restraints and wheelchair accessories, which are medical devices within the meaning of § 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 USC 321]. The protective restraints you manufacture are Class I medical devices not exempt from the current good manufacturing practice (CGMP) requirements of the Quality System (QS) regulations, as specified in Title 21, *Code of Federal Regulations*, Part 820 (21 CFR 820). You can find the Act and the CFR through links in FDA's home page at http://www.fda.gov.

The above-stated inspection revealed the devices to be adulterated within the meaning of Section 501(h) of the Act [21 USC 351(h)] in that the methods used in, or the facilities or controls used for, the manufacture, packing, storage, or installation of your protective restraint are not in conformity with the CGMPs. Specific violations of the QS regulations include:

1. Failure of management with executive responsibility to ensure an adequate and effective quality system has been fully implemented and maintained at all levels of the organization, as required by 21 CFR 820.20. Specifically, your firm has not implemented a quality program and does not have designated individuals to perform quality functions.

2. Failure to establish procedures for acceptance or rejection of finished device production runs, lots, or batches, as required by 21 CFR 820.80(d). Specifically, your firm does not have written procedures for accepting or rejecting medical device production runs prior to distribution.

3. Finished devices were released for distribution without signature of the individual designated to authorize such release, as required by 820.80(d)(3). Specifically, your firm fails to authorize release of medical devices prior to distribution.

4. Failure to document acceptance activities, as required by 21 CFR 820.80(e). Specifically, your firm does not document in-process and finished device testing inspections.

5. The device master record fails to include or refer to the location of production and process specifications, as required by 21 CFR 820.181(b). Specifically, your firm does not have device master records for production activities.

6. The quality system record fails to include or refer to quality system procedures and documentation of quality system activities, as required by 21 CFR 820.186. Specifically, your firm fails to have a quality system record that refers to quality system procedures and documentation of quality system activities.

7. Failure to establish procedures to ensure device history records for each batch, lot, or unit are maintained to demonstrate the device is manufactured in accordance with the device master record and QS regulations, as required by 21 CFR 820.184. Specifically, your firm does not have a procedure for establishing device history records.

8. The device history record fails to demonstrate the device is manufactured in accordance with the device master record, as required by 21 CFR 820.184. Specifically, your firm does not have or maintain device history records.

9. Failure to establish a formally designated unit for handling complaints, as required by 21 CFR 820.198(a). Specifically, your firm does not have a designated individual or unit to handle consumer complaints. This requirement, as well as the one below, applies not just to the protective restraints you manufacture but also to the wheelchair accessories.

10. Failure to establish complaint handling procedures for receiving, reviewing, and evaluating complaints, as required by 21 CFR 820.198(a). Specifically, your firm does not have a written procedure for handling and evaluating consumer complaints.

11. Failure to establish document control procedures, as required by 21 CFR 820.40. Specifically, your firm does not have a written procedure concerning the approval of procedures and specifications.

12. The documentation of approval of documents fails to include the signature of the approving official, as required by 21 CFR 820.40(a). Specifically, there are no signatures indicating approval of written procedures.

13. Failure to establish procedures for conducting quality audits, as required by 21 CFR 820.22. Specifically, your firm does not have procedures for conducting quality audits.

14. Failure to conduct quality audits to verify the quality system is effective in fulfilling quality system objectives, as required by 21 CFR 820.22. Specifically, your firm does not conduct quality audits.

15. Failure to establish the quality policy and objectives, as required by 21 CFR 820.20(a). Specifically, your firm does not have a quality policy.

16. Failure to establish procedures for identifying training needs, as required by 21 CFR 820.25(b). Specifically, your firm does not have written procedures or training program for training employees.

17. Failure to document employee training, as required by 21 CFR 820.25(b). Specifically, there is no documentation indicating employees have been trained to adequately perform their assigned responsibilities.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the FDA 483 issued at the close of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by FDA. You also must promptly initiate permanent corrective and preventive action on your Quality System.

Federal agencies are advised of the issuance of all warning letters about devices so they may take this information into account when considering the award of contracts. Additionally, no requests for Certificates to Foreign Governments will be approved until the violations related to the subject devices have been corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office in writing within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure similar violations will not recur.

If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the time within which the corrections will be completed. Your reply should be directed to the attention of Kimberly L. McMillan, Compliance Officer, 297 Plus Park Boulevard, Nashville, TN 37217. If you have any questions concerning the violations noted, please contact Ms. McMillan at (615) 781-5380 extension 138.

Sincerely,

H. Tyler Thornburg
Director, New Orleans District

Enclosures:
Form FDA 483
Quality System Regulation 21 CFR 820